Application Serial No.: 10/076,900 UPAP0003-100 (136622)

Response to Election Requirement dated June 3, 2003

Preliminary Amendment and Reply to Election Requirement dated September 3, 2003

Amendments to the Claims:

Please amend claims 15 and cancel claims 17-26 and 55-80 and add claims 81-107

Claims 1-14 (Cancelled)

15. (Currently Amended) A method of inducing in an individual an immune response against an antigen

wherein said immune response includes both a humoral immune response that includes a mucosal immune response and a cellular immune response that includes antigen specific cytotoxic T lymphocytes;

the method comprising the step of administering by topical or lavage administration to <u>sublingual</u> mucosal tissue of said individual, <u>said mucosal tissue is selected from the group</u> eonsisting of rectal, vaginal, urethral, sublingual and buccal, a nucleic acid molecule that is free of an <u>infectious infection</u> agent and comprises a nucleotide sequence that encodes said antigen operably linked to regulatory sequences in an amount effective to induce an immune response against said antigen wherein said immune response includes both a humoral immune response that includes a mucosal immune response and a cellular immune response.

16. (Previously Presented) The method of claim 15 wherein the antigen is a pathogen antigen.

Claims 17-38 (Cancelled)

- 39. (Previously Presented) The method of claim 15 wherein the immune response is a therapeutically effective immune response and said nucleic acid molecule is administered in an amount effective to induce a therapeutically effective immune response against said antigen.
- 40. (Previously Presented) The method of claim 39 wherein the antigen is a pathogen antigen.

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41. (Previously Presented) The method of claim 40 wherein the pathogen antigen is a viral antigen.

- 42. (Previously Presented) The method of claim 41 wherein the viral antigen is an antigen from human immunodeficiency virus.
- 43. (Previously Presented) The method of claim 42 wherein antigen from human immunodeficiency virus comprises an epitope of human immunodeficiency virus protein gp160.
- 44. (Previously Presented) The method of claim 43 wherein said nucleic acid molecule is administered to said individual in a composition that further comprises bupivacaine.
- 45. (Previously Presented) The method of claim 15 wherein the immune response is a prophylactically effective immune response and said nucleic acid molecule is administered in an amount effective to induce a prophylactically effective immune response against said antigen.
- 46. (Previously Presented) The method of claim 45 wherein the antigen is a pathogen antigen.
- 47. (Previously Presented) The method of claim 46 wherein the pathogen antigen is a viral antigen.
- 48. (Previously Presented) The method of claim 47 wherein the viral antigen is an antigen from human immunodeficiency virus.
- 49. (Previously Presented) The method of claim 48 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.
- 50. (Previously Presented) The method of claim 49 wherein said nucleic acid molecule is administered to said individual in a composition that further comprises bupivacaine.
- 51. (Previously Presented) The method of claim 16 wherein the pathogen antigen is a viral antigen.

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- 52. (Previously Presented) The method of claim 51 wherein the viral antigen is an antigen from human immunodeficiency virus.
- 53. (Previously Presented) The method of claim 52 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.
- 54. (Previously Presented) The method of claim 53 wherein said nucleic acid molecule is administered to said individual in a composition that further comprises bupivacaine.

Claims 55-80. (Cancelled)

- 81. (New) The method of claim 15 wherein said nucleic acid molecule is administered to said individual in a composition that comprises a nucleic acid molecule which comprises a nucleotide sequence that encodes: a cytokine operatively linked to regulatory sequences which control the expression of said nucleotide sequence; and/or a nucleotide sequence that encodes a lymphokine, said nucleotide sequence operatively linked to regulatory sequences which control the expression of said nucleotide sequence.
- 82. (New) The method of claim 81 wherein said composition comprises bupivacaine.
- 83. (New) The method of claim 81 wherein said composition comprises a nucleic acid molecule which comprises a nucleotide sequence that encodes a protein operatively linked to regulatory sequences which control the expression of said nucleotide sequence, wherein said protein is selected form the group consisting of .alpha.-interferon, gamma-interferon, platelet derived growth factor (PDGF), GC-SF, GM-CSF, TNF, epidermal growth factor (EGF), IL-1, IL-2, IL-4, IL-6, IL-8, IL-10 and IL-12.
- 84. (New) The method of claim 83 wherein said composition comprises bupivacaine.

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- 85. (New) The method of claim 83 wherein said protein is IL-12.
- 86. (New) The method of claim 85 wherein said composition comprises bupivacaine.
- 87. (New) The method of claim 16 wherein said nucleic acid molecule is administered to said individual in a composition that comprises a nucleic acid molecule which comprises a nucleotide sequence that encodes: a cytokine operatively linked to regulatory sequences which control the expression of said nucleotide sequence; and/or a nucleotide sequence that encodes a lymphokine, said nucleotide sequence operatively linked to regulatory sequences which control the expression of said nucleotide sequence.
- 88. (New) The method of claim 87 wherein said composition comprises bupivacaine.
- 89. (New) The method of claim 87 wherein the pathogen antigen is a viral antigen.
- 90. (New) The method of claim 89 wherein the viral antigen is an antigen from human immunodeficiency virus.
- 91. (New) The method of claim 90 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.
- 92. (New) The method of claim 87 wherein said composition comprises bupivacaine.
- 93. (New) The method of claim 87 wherein said composition comprises a nucleic acid molecule which comprises a nucleotide sequence that encodes a protein operatively linked to regulatory sequences which control the expression of said nucleotide sequence, wherein said protein is selected form the group consisting of .alpha.-interferon, gamma-interferon, platelet derived growth factor (PDGF), GC-SF, GM-CSF, TNF, epidermal growth factor (EGF), IL-1, IL-2, IL-4, IL-6, IL-8, IL-10 and IL-12.

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- 94. (New) The method of claim 93 wherein said composition comprises bupivacaine.
- 95. (New) The method of claim 93 wherein the pathogen antigen is a viral antigen.
- 96. (New) The method of claim 95 wherein the viral antigen is an antigen from human immunodeficiency virus.
- 97. (New) The method of claim 96 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.
- 98. (New) The method of claim 97 wherein said composition comprises bupivacaine.
 - 99. (New) The method of claim 93 wherein said protein is IL-12.
- 100. (New) The method of claim 99 wherein said composition comprises bupivacaine.
- 101. (New) The method of claim 99 wherein the pathogen antigen is a viral antigen.
- 102. (New) The method of claim 101 wherein the viral antigen is an antigen from human immunodeficiency virus.
- 103. (New) The method of claim 102 wherein antigen from human immunodeficiency virus comprise an epitope of human immunodeficiency virus protein gp160.
- 104. (New) The method of claim 103 wherein said composition comprises bupivacaine.
- 105. (New) The method of claim 16 wherein said composition comprises bupivacaine.

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106. (New) The method of claim 105 wherein the pathogen antigen is a viral antigen.

107. (New) The method of claim 106 wherein the viral antigen is an antigen from human immunodeficiency virus.